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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0790]

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Final Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#106) entitled ''The Use of Published Literature in Support of New Animal Drug Approval.'' The final guidance is intended to fulfill the section of the FDA Modernization Act of 1997 (FDAMA) that requires the agency to issue guidance to clarify the circumstances in which published matter may be the basis for approval of a supplemental application. The final guidance also clarifies the circumstances in which published literature may be the basis for approval of an original application. The final guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approvals.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the final guidance may be obtained on the Internet at http://www.fda.gov/cvm/fda/TOCs/guideline.html.

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FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 19, 2000 (65 FR 20997), FDA published the draft guidance entitled ''The Use of Published Literature in Support of New Animal Drug Approval'' giving interested persons until July 18, 2000, to submit comments. No comments were received.

Section 403(b) of FDAMA (Public Law 105–115) requires FDA to issue guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision includes a requirement that FDA publish guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application.

This final guidance for industry clarifies the circumstances in which published literature may be the basis for approval of both original and supplemental new animal drug applications. Specifically, the final guidance describes the circumstances under which FDA could rely on published literature without access to the underlying data and the circumstances under which the applicant should provide additional information about a published study.

II. Significance of Guidance

This final guidance represents the agency's current thinking with regard to the use of published literature in support of new animal drug approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of the applicable statutes and regulations. The agency has developed this final guidance in accordance with the agency's good guidance practices

published in the **Federal Register** of September 19, 2000 (65 FR 56468), which set forth the policies and procedures for the development, issuance, and use of guidance documents.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review

the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: 10/30/00

October 30, 2000.

Margaret M. Dotzel,
Associate Commisioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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